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08/398,555	03/03/1995	LINDA G. CIMA	MIT6210	7254

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EXAMINER

RUSSEL, JEFFREY E

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/398,555

Applicant(s)

CIMA ET AL.

Examiner

Jeffrey E. Russel

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to *the Board decision mailed* communication(s) filed on 27 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17 and 32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-17 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s) 33
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other

Art Unit: 1653

1. The period for seeking court review of the decision by the Board of Patent Appeals and Interferences rendered July 27, 2001 has expired and no further action has been taken by appellant. The proceedings as to the rejected claims are considered terminated; see 37 CFR 1.197(c). It is suggested that in the response to this Office action, Applicants cancel the claims whose final rejection was upheld by the Board. Further, Applicants should also re-write claim 14 in independent form, including all of the limitations set forth in claim 13 upon which it depends.

The amendment after final rejection filed July 21, 1997 has not been entered for the reasons set forth in the decision on petition mailed December 15, 1997 and because, as noted above, proceedings are terminated with respect to all claims other than claims 14-17 and 32.

The following grounds of rejection are made pursuant to the remand included in the decision by the Board of Patent Appeals and Interferences rendered July 27, 2001:

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 14-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 5,906,828. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Art Unit: 1653

Assuming that a one-way test is appropriate for obviousness-type double patenting, then the instant generic claims are anticipated by the narrower claims of the '828 patent and one-way obviousness (i.e. of the instant claims over the claims of the '828 patent) is therefore satisfied.

4. Claim 32 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 20 of U.S. Patent No. 6,045,818. Although the conflicting claims are not identical, they are not patentably distinct from each other. Assuming that a one-way test is appropriate for obviousness-type double patenting, then the instant generic claims are anticipated by the narrower claims of the '818 patent and one-way obviousness (i.e. of the instant claims over the claims of the '818 patent) is therefore satisfied.

5. In the telephone interview on November 7, 2001, Applicants mentioned several cases relevant to the obviousness-type double patenting issues in this application. These cases are *In re Goodman*, 29 USPQ2d 2010 (CAFC 1993); *In re Braat*, 19 USPQ2d 1289 (CAFC 1991); *In re Borah*, 148 USPQ 213 (CCPA 1966); *In re Berg*, 46 USPQ2d 1226 (CAFC 1998); and *In re Emert*, 44 USPQ2d 1149 (CAFC 1997).

Assuming that a one-way test of obviousness-type double patenting is required by the instant fact situation, then this test is met because the claims of the issued patents anticipate the instant more generic claims.

The examiner does not agree that a two-way test for obviousness-type double patenting is required. The most recent of the cases cited by Applicants discussing whether a one-way test or a two-way obviousness-type double patenting test is appropriate, Berg, emphasizes that the "[t]he two-way test, however, is a narrow exception to the general rule of the one-way test" (Berg at page 1229, last full paragraph). The court in Berg also distinguished the Braat decision

Art Unit: 1653

on the basis that the disclosures of the Berg application and the Berg patent were identical, whereas in Braat, the later-filed application/patent was an improvement over and a continuation-in-part of the first-filed application (see page 1231, first full paragraph). The facts in the instant application are more similar to Berg than to Braat because the disclosures of the instant application and the later-filed application/patent are identical, i.e. the later-filed application/patent is a continuation, not a continuation-in-part, of the instant application. The facts of the instant application are also similar to the facts in Goodman as summarized by the Berg court (see Berg at page 1231, second full paragraph). In Goodman, claims drawn to the species were allowed and the genus claims were subsequently rejected over the issued species claims. In the instant application, claims drawn to the species were allowed, and now the genus claims are being rejected over the issued species claims. As was held in Goodman and confirmed in Berg, a one-way test of obviousness-type double patenting is appropriate for this fact situation. The court in Berg addresses the instant fact situation in which species claims are issued prior to conclusion of examination of the genus claims and an obviousness-type double patenting rejection of the genus claims over the species claims is made (see Berg at page 1233, first full paragraph). The court quotes the policy in favor of the obviousness-type double patenting rejection as set forth in MPEP 804.02: "the use of a terminal disclaimer in overcoming a nonstatutory double patenting rejection is in the public interest because it encourages the disclosure of additional developments, the earlier filing of applications, and the earlier expiration of patentees whereby the inventions covered become freely available to the public". As finally summarized by Berg at page 1233, second full paragraph, "If an applicant could have filed both sets of claims in a single application because the disclosure of the first application supports the

Art Unit: 1653

second set of claims, then pursuant to this case and Goodman, the one-way test is appropriate to determine if a rejection for obviousness-type double patenting should be sustained". This is the fact situation in the instant application, and a one-way test for obviousness-type double patenting is appropriate.

6. Instant claims 14-17, in combination with the European Patent Application '733, are not deemed to suggest the claimed invention of U.S. Patent No. 5,906,828. Instant claims 14-17 are directed to growing eukaryotic cells in vivo, whereas the European Patent Application '733 is directed to carriers for in vitro animal cell cultures. There is no motivation to look to the in vitro cell culture art as represented by the European Patent Application '733 in order to provide a spacer or tether for use in the in vivo systems claimed in instant claims 14-17. Such a combination is mere hindsight reconstruction of the claimed invention of the '828 patent, and as such is improper. Accordingly, two-way obviousness double patenting does not exist between instant claims 14-17 and the claims of the '828 patent.

Claim 32 is not rendered obvious by the claims of U.S. Patent No. 5,906,828. The assay for compound activity claimed in the '828 patent does not render obvious the in vivo method of growing eukaryotic cells, and vice versa.

Claims 14-17 are not rendered obvious by the claims of U.S. Patent No. 6,045,818, and in particular by claims 9-18 of the patent, because the claims of the '818 patent do not teach or suggest growing eukaryotic cells in vivo in a patient. The ability to cause cell growth in vitro does not in and of itself provide any motivation to cause cell growth in vivo in a patient and does not in and of itself provide a reasonable expectation of success that cell growth in vivo in a patient could be achieved.

Art Unit: 1653

Instant claim 32 is not deemed to render obvious claim 20 of U.S. Patent No. 6,045,818 because instant claim 32 does not teach or suggest the particular tethers recited in claim 20 of the '818 patent. Note also that the particular tethers recited in claim 20 of the '818 patent are not suggested by or analogous to the polyethyleneimine tether of the European Patent Application '733.

7. The three prior art rejections which were vacated in the decision by the Board of Patent Appeals and Interferences mailed July 27, 2001 (see page 9 of the decision) are hereby reiterated. In particular:

(1) Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herweck et al in view of Merrill (U.S. Patent No. 5,171,264) for the same reasons set forth in the Examiner's Answer mailed January 12, 1998.

(2) Claim 17 is rejected under 35 U.S.C. 103(a) as being obvious over Herweck et al in view of Merrill (U.S. Patent No. 5,171,264) and further in view of Mikos for the same reasons set forth in the Examiner's Answer mailed January 12, 1998.

(3) Claims 14-17 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application '616 for the same reasons set forth in the Examiner's Answer mailed January 12, 1998.

In vacating these rejections, the Board expressed concern that instant claims 14-17 were not patentably distinct from claims in a subsequently filed continuation application which issued as U.S. Patent No. 5,906,828. However, the claims in the '828 patent are clearly patentably distinct over the broader claims pending in the instant application. See section 6, first full paragraph, of this Office action. In view of this patentable distinction, there is of course no

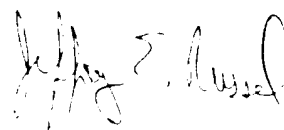
Art Unit: 1653

conflict in the examiner's holding that the broader claims present in the instant application are unpatentable, whereas the narrower claims issued in U.S. Patent No. 5,906,828 are patentable.

The examiner re-iterates that the claims of U.S. Patent No. 5,906,828 are patentable. Herweck et al in combination with Merrill do not teach or suggest a growth effector molecule concentration which enhances the rate of target cell growth over the rate of target cell growth with growth effector molecules adsorbed to a substrate. Neither the WO Patent Application '616 nor the European Patent Application '733, alone or in combination, suggest the claimed invention of the '828 patent because the patent claims require the in vivo administration of the eukaryotic cell growth stimulating composition and require the use of a branched water-soluble polymeric tether, whereas the European Patent Application '733 does not teach or suggest the in vivo administration of their compositions, and the WO Patent Application '616 does not teach or suggest the use of a branched water-soluble polymeric tether.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Christopher Low can be reached at (703) 308-2923. The fax number for Art Unit 1653 for formal communications is (703) 305-3014; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1 receptionist is (703) 308-0196.



Jeffrey E. Russel
Primary Patent Examiner
Art Unit 1653

JRussel
March 15, 2002



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